

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** ( Not for submission under 37 CFR 1.99)

Application Number		10598116
Filing Date		2006-08-17
First Named Inventor	Margaret Anne Butlin	
Art Unit		
Examiner Name		
Attorney Docket Number	101358-1P US	

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	1	5464853		1995-11-07	Chan, Ming F., et al.	
	2	5514691		1996-05-07	Chan, Ming F., et al.	
	3	5843902		1998-12-01	Garnick, Marc B., et al.	
	4	6197967	B1	2001-03-06	Vollmueller, Frank, et al.	

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	1	20050014769	A1	2005-01-20	Osswald, Mathias, et al.	
	2	20020055457	A1	2002-05-09	Janus, Todd J., et al.	

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3	20030092757	A1	2003-05-15	Singh, Amitabh, et al.	
4	20020107284	A1	2002-08-08	Uckun, Faith M., et al.	

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	1	1995/26957	WO	A1	1995-10-12	Zeneca Ltd.		<input type="checkbox"/>
	2	1998/40332	WO	A1	1998-09-17	Zeneca Ltd.		<input type="checkbox"/>
	3	2004/018044	WO	A2	2004-03-04	AstraZeneca AB		<input type="checkbox"/>
	4	2004/032922	WO	A1	2004-04-22	AstraZeneca AB		<input type="checkbox"/>
	5	2004/035057	WO	A1	2004-04-29	AstraZeneca AB		<input type="checkbox"/>
	6	2005/023264	WO	A1	2005-03-17	AstraZeneca AB		<input type="checkbox"/>
	7	2006/056760	WO	A1	2006-06-01	AstraZeneca AB		<input type="checkbox"/>

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8	2007/010235	WO	A1	2007-01-25	AstraZeneca AB		<input type="checkbox"/>
9	1994/27979	WO	A1	1994-12-08	Immunopharmaceutics, Inc.		<input type="checkbox"/>
10	2001/00198	WO	A2	2001-01-04	CA Institute of Technology		<input type="checkbox"/>
11	2000/67024	WO	A1	2000-11-09	New York University		<input type="checkbox"/>
12	2001/60370	WO	A1	2001-08-23	Yamanouchi Pharmaceutical Co., Ltd.		<input checked="" type="checkbox"/>
13	1999/56761	WO	A1	1999-11-11	Gudarz Davar		<input type="checkbox"/>
14	2002/11713	WO	A2	2002-02-14	Abbott Laboratories		<input type="checkbox"/>
15	2000/36918	WO	A1	2000-06-29	Marine Polymers Technologies Inc.		<input type="checkbox"/>
16	2002/085351	WO	A1	2002-10-31	Abbott Laboratories		<input type="checkbox"/>
17	2002/49630	WO	A2	2002-06-27	Bristol-Myers Squibb Company		<input type="checkbox"/>
18	2001/91736	WO	A2	2001-12-06	Warner-Lambert Company		<input type="checkbox"/>

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19	2001/44239	WO	A2	2001-06-21	Bristol-Myers Squibb Company		<input type="checkbox"/>
20	2003/045434	WO	A2	2003-06-05	The Board of Trustees of the University of IL		<input type="checkbox"/>
21	2003/006041	WO	A1	2003-01-23	Takeda Chemical Industries, Ltd.		<input checked="" type="checkbox"/>
22	2003/015820	WO	A1	2003-02-27	Takeda Chemical Industries, Ltd.		<input checked="" type="checkbox"/>
23	1999/48530	WO	A1	1999-09-30	Merck & Co., Inc.		<input type="checkbox"/>
24	2002/074034	WO	A2	2002-09-26	Boehringer Ingelheim Pharma KG		<input checked="" type="checkbox"/>
25	2002/080960	WO	A2	2002-10-17	Medical Research Council		<input type="checkbox"/>
26	2002/69906	WO	A2	2002-09-12	Cellegy Pharmaceuticals, Inc.		<input type="checkbox"/>
27	2003/009805	WO	A2	2003-02-06	Brigham and Women's Hospital, Inc.		<input type="checkbox"/>
28	2000/21509	WO	A2	2000-04-20	Imperial College Innovations Limited		<input type="checkbox"/>
29	1996/09818	WO	A1	1996-04-04	Merck & Co., Inc.		<input type="checkbox"/>

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30	2003/039539	WO	A2	2003-05-15	Merck Patent Gmbh		<input checked="" type="checkbox"/>
31	1999/55683	WO	A1	1999-11-04	Pfizer Products Inc.		<input type="checkbox"/>
32	2005/063735	WO	A1	2005-07-14	Merck Patent GMBH		<input checked="" type="checkbox"/>
33	0682016	EP	A1	1995-11-15	Zeneca Ltd.		<input type="checkbox"/>
34	0749964	EP	A1	1996-12-27	Zeneca Ltd.		<input type="checkbox"/>
35	0510526	EP	A1	1992-10-28	F. Hoffmann-La Roche & Co.		<input checked="" type="checkbox"/>
36	0526708	EP	A1	1993-02-10	F. Hoffman-La Roche AG		<input checked="" type="checkbox"/>
37	0558258	EP	A1	1993-09-01	E.R. Squibb & Sons, Inc.		<input type="checkbox"/>
38	0569193	EP	A1	1993-11-10	E.R. Squibb & Sons, Inc.		<input type="checkbox"/>
39	0640596	EP	A1	1995-03-01	Bristol-Myers Squibb Co.		<input type="checkbox"/>
40	1256344	EP	A1	2002-11-13	Yamanouchi Pharmaceutical Co., Ltd.		<input type="checkbox"/>

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41	1424080	EP	A1	2004-06-02	Takeda Chemical Industries, Ltd.		<input type="checkbox"/>
42	2295616	GB	A1	1996-06-05	Zeneca Ltd.		<input type="checkbox"/>
43	1996/40681	WO	A1	1996-12-19	Zeneca Ltd.		<input type="checkbox"/>

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	1	MORRIS, MICHAEL J. ET AL., Clinical approaches to osseous metastases in prostate cancer, The Oncologist, 2003, pages 161-173, vol. 8, no. 2.	<input type="checkbox"/>
	2	ROSANO, LAURA A. ET AL., Therapeutic targeting of the endothelin a receptor in human ovarian carcinoma, Cancer Research, 15 May 2003, pages 2447-2453, vol. 63, no. 10, XP002365689.	<input type="checkbox"/>
	3	WALCZAK J. R. ET AL., Pharmacological Treatments for Prostate Cancer, Expert Opinion on Investigational Drugs, 2002, pages 1737-1748, vol. 11, no. 12, XP009008862.	<input type="checkbox"/>
	4	ROSANO, LAURA ET AL., ZD4054, a specific antagonist of the endothelin A receptor, inhibits tumor growth and enhances cytotoxicity of paclitaxel in human ovarian carcinoma in vitro and in vivo, April 16-20, 2005, AACR, Anaheim/Orange County, CA.	<input type="checkbox"/>
	5	CURTIS, N. ET AL., ZD4054 specifically inhibits endothelin A receptor-mediated anti-apoptotic effects, but not endothelin B receptor-mediated pro-apoptotic effects, September 28-October 1, 2004, AACR-NCI-EORTC, Geneva, Switzerland.	<input type="checkbox"/>
	6	LIU, GLENN ET AL., Tolerability profile of ZD4054 is consistent with the effects of endothelin A receptor-specific antagonism, May 13-17, 2005, ASCO Annual Meeting, Orlando, Florida.	<input type="checkbox"/>

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7	MORRIS, C. ET AL., ZD4054: specificity for endothelin A receptor following single-dose administration in healthy volunteers, September 28-October 1, 2004, AACR-NCI-EORTC, Geneva, Switzerland.	<input type="checkbox"/>
8	DREICER, R. ET AL., ZD4054 specifically inhibits endothelin A receptor-mediated effects but not endothelin B receptor-mediated effects, February 17-19, 2005, ASCO Prostate Cancer Symposium, Orlando, Florida.	<input type="checkbox"/>
9	TODD, MARTIN ET AL., Metabolite Factories: Use of microbial systems to generate metabolites of an endothelin receptor antagonist, July 3-8, 2005, Biotrans 2005, Delft, The Netherlands.	<input type="checkbox"/>
10	MORRIS, C.D. ET AL., Specific inhibition of the endothelin A receptor with ZD4054: clinical and preclinical evidence, British Journal of Cancer, 2005, 2148-2152, vol. 92.	<input type="checkbox"/>
11	CURTIS, N. ET AL., ZD4054 blocks ET-1-stimulated phosphorylation of p44/42 mitogen-activated protein kinase and proliferation of osteoblast cells, April 16-20, 2005, AACR, Anaheim/Orange County, CA.	<input type="checkbox"/>
12	MORRIS, C.D. ET AL, ZD4054 reduces endothelin-1-induced forearm vasoconstriction in healthy male volunteers, April 16-20, 2005, AACR, Anaheim/Orange County, CA.	<input type="checkbox"/>
13	ROSANO, LAURA ET AL, Combined targeting of the endothelin receptor and the epidermal growth factor receptor in ovarian cancer shows enhanced antiproliferative effects, April 1-5, 2006, AACR 2006, Washington, DC.	<input type="checkbox"/>
14	CURWEN, J.O., ZD4054 : A specific endothelin A receptor antagonist with potential utility in prostate cancer and metastatic bone disease, European Journal of Cancer, November 2002, page S102, vol. 38, XP004403782.	<input type="checkbox"/>
15	NELSON, J.B., The role of endothelin-1 and endothelin receptor antagonists in prostate cancer, British Journal of Urology, 2000, pages 45-48, 85, Suppl 2.	<input type="checkbox"/>
16	Endothelin Inhibitors: Exploring Novel Therapeutics, Symposium, June 7-8, 1999, Washington, D.C., Iddb Meeting Report, 25 June 1999.	<input type="checkbox"/>
17	BOVEN, E., American Society of Clinical Oncology-35th Annual Meeting (Part 1), Symposium, May 15-18, 1999, Atlanta, GA, Iddb Meeting Report, 13 September 2001.	<input type="checkbox"/>

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18	MCKINNON, C., American Society of Clinical Oncology-35th Annual Meeting (Part IV), Symposium, May 15-18, 1999, Atlanta, GA, Iddb Meeting Report, 13 September 2001.	<input type="checkbox"/>
19	ADENIYI, A., American Urological Association-94th Annual Meeting, Symposium, May 1-6, 1999, Dallas, TX, Iddb Meeting Report, 26 August 1999.	<input type="checkbox"/>
20	MCKINNON, C., Topoisomerase inhibitors and other new agents, ID Drugs, 1999, pages 629-632, Vol. 2, No. 7.	<input type="checkbox"/>
21	ADENIYI, A., American Urological Association-94th Annual Meeting May 1-6, 1999, Dallas, TX, ID Drugs, 1999, pages 656-658 Vol. 2, No. 7.	<input type="checkbox"/>
22	BOVEN, E., American Society of Clinical Oncology-35th Annual Meeting, 15-18 May 1999, Atlanta, GA, ID Drugs, 1999, pages 617-619, Vol. 2, No. 7.	<input type="checkbox"/>
23	NELSON, JOEL B., Editorial: Endothelin Receptor Antagonists in the Treatment of Prostate Cancer, The Prostate, pages 91-92, 2001, Volume 49.	<input type="checkbox"/>
24	NELSON, JOEL B., The Role of the Endothelin Axis in Prostate Cancer, The Prostate Journal, pages 126-130, 1999, Volume 1, No. 3.	<input type="checkbox"/>
25	NELSON, JOEL B. ET AL, Identification of endothelin-1 in the pathophysiology of metastatic adenocarcinoma of the prostate, Nature Medicine, pages 944-949, September 1995, Volume 1, No. 9.	<input type="checkbox"/>
26	CARDUCCI, MICHAEL A. ET AL, Endothelin Receptor Antagonist, ABT-627, For Prostate Cancer: Initial Trial Results, The Journal of Urology, page 176, 1999, Volume 161(4) Suppl.	<input type="checkbox"/>
27	JARVIS, MICHAEL F., ET AL., ABT-627, an endothelin ETA receptor-selective antagonist, attenuates tactile allodynia in a diabetic rat model of neuropathic pain, European Journal of Pharmacology, pages 29-35, 2000, Vol. 388. No. 1.	<input type="checkbox"/>
28	BAGNATO, ANNA, ET AL., Autocrine Actions of Endothelin-1 as a Growth Factor in Human Ovarian Carcinoma Cells, Clinical Cancer Research, 1995, pages 1059-1066, Vol. 1.	<input type="checkbox"/>



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29	WU-WONG, JINSHYUN R., Endothelin attenuates apoptosis in human smooth muscle cells, Biochemical Journal, pages 733-737, 1997, Vol. 328.	<input type="checkbox"/>
30	SPINELLA, FRANCESCA, ET AL., Endothelin-1 Induces Vascular Endothelial Growth Factor by Increasing Hypoxia-inducible Factor-1a in Ovarian Carcinoma Cells, The Journal of Biological Chemistry, pages 27850-27855, August 2, 2002, Volume 277, No. 31.	<input type="checkbox"/>
31	KROODSMA, J.M., ET AL., Endothelinen: modelijk een nieuw farmacologisch aangrijpingspunt bij hartvaatziekten, nierziekten en oncologische aandoingen, Nederlands Tijdschrift Voor Geneeskunde, 1997, pages 1806-1810, Volume 141, Part 38.	<input checked="" type="checkbox"/>
32	NELSON, JOEL B. ET AL., Endothelin-1 Production and Decreased Endothelin B Receptor Expression in Advanced Prostate Cancer, Journal of Cancer Research, February 15, 1996, pages 663-668, Volume 56.	<input type="checkbox"/>
33	Derwent AN 2001-565331, XP002271565.	<input type="checkbox"/>
34	PIETTRE, SERGE R., ET AL., Monoaryl- and Bisaryldihydroxytropolones as Potent Inhibitors of Inositol Monophosphatase, Journal of Medicinal Chemistry, 1997, pages 4208-4221, vol. 40.	<input type="checkbox"/>

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**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Lucy Padget/	Date (YYYY-MM-DD)	13 April 2007
Name/Print	Lucy Padget	Registration Number	L0074

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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